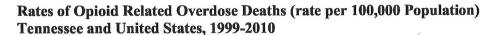
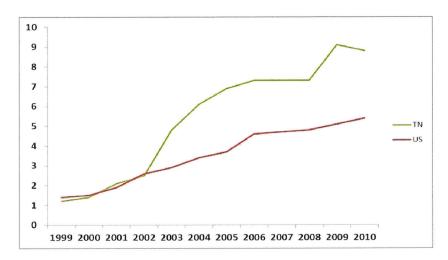
## **EXHIBIT 6 PART 2**

each year for the number of opioid overdose deaths, with 2,388 in 2020 alone. 194 The rate in 2020 equated to more than 6 opioid overdose deaths in Tennessee every single day.





Between 2005 and 2015, just one decade, unintentional overdose deaths in Tennessee increased over 250%. Unintentional overdose deaths now account for more early deaths in Tennessee than automobile accidents, suicides, or homicides. 195

- Defendants also contributed to NAS deaths in Tennessee. NAS is a clinical 438. diagnosis, and "a consequence of the abrupt discontinuation of chronic fetal exposure to substances that were used or abused by the mother during pregnancy." <sup>196</sup>
- According to a report produced by Governor Bill Haslam's Opioid Abuse Working 439. Group pursuant to 2015 Tenn. Pub. Acts Ch. 389 ("Governor's Working Group Report"), "[t]he

<sup>&</sup>lt;sup>194</sup> *Id*.

<sup>&</sup>lt;sup>195</sup> Working Group Report at 4.

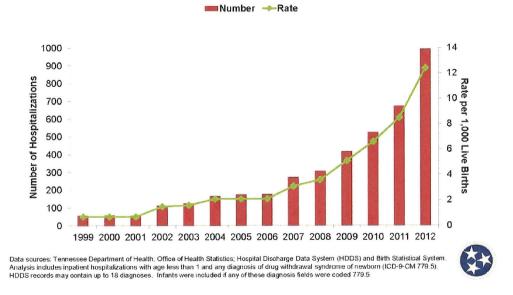
<sup>&</sup>lt;sup>196</sup> Prabhakar Kocherlakota, Neonatal Abstinence Syndrome, 134(2) Pediatrics 547, 547-48 (2014), available at http://pediatrics.aappublications.org/content/pediatrics/134/2/e547.full.pdf.



number of babies born with Neonatal Abstinence Syndrome (NAS)... increased tenfold from 2000 to 2010."197 Since 2010, the problem has only gotten worse.

440. Along with overdose deaths, the number and rate of NAS – a condition suffered by babies born to mothers addicted to opioids – has also increased dramatically in Tennessee since 2007:

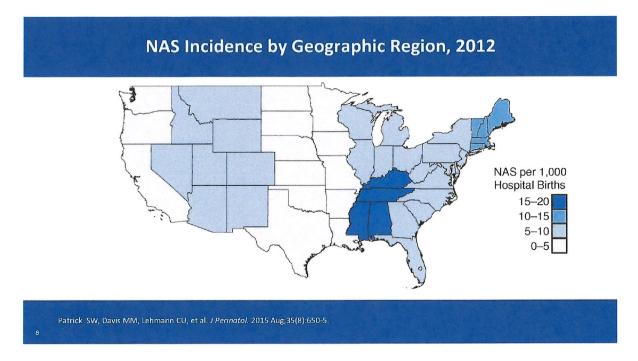
# NAS Hospitalizations in TN: 1999-2012



441. As illustrated by the following map, researchers analyzing hospital discharge data have determined that Tennessee, along with its border states Kentucky, Alabama, and Mississippi, have the highest rates of NAS births in the nation. 198

<sup>&</sup>lt;sup>197</sup> Working Group Report at 4 (emphasis added).

<sup>&</sup>lt;sup>198</sup> Stephen W. Patrick et al., *Increasing Incidence of Neonatal Abstinence Syndrome: United States 2009-2012*, 35(8) J. Peronatol. 650, 650-55.



- 442. The percentage of pregnant women served by the Tennessee Department of Mental Health & Substance Abuse Services—42.3% in 2012—listing prescription opioids as their primary substance of abuse was over twice the percentage in the United States overall (18.4% in 2012).
- 443. TennCare eligibility records establish that 24.3% of babies born with NAS in 2012 were placed in the Department of Children's Services' custody within one year of birth. 199
- 444. The epidemic of NAS babies is an outgrowth of the explosion in the amount of opioids in Tennessee since the mid-1990s. As the Appalachia HIDTA recognized in its 2015 Annual Report:

[T]he state of Tennessee and east Tennessee in particular, is plagued by an epidemic of opioid abuse, which has unfortunately now resulted in a resurgence of heroin as a growing threat. A consequence of this opioid abuse is the alarming number of children being born dependent on opioids, afflicted with Neonatal Abstinence Syndrome (NAS). Children born with NAS suffer extreme physical symptoms of withdrawal and require specialized care in the neonatal wards of hospitals. This

<sup>199</sup> Working Group Report at 4.

treatment often consists of children being given smaller doses of methadone or similar drugs, over time, to break their addiction to opioids.<sup>200</sup>

445. The direct link between the flood of prescription opioids and the NAS baby crisis in Tennessee has been clearly stated by Tennessee's Commissioner of Health Dr. John Dreyzehner. In a 2015 presentation entitled "Neonatal Abstinence Syndrome: A Tennessee Perspective," Commissioner Dreyzehner addressed "the Substance Abuse Epidemic and resulting NAS epidemic." <sup>201</sup>

446. In his NAS presentation, Commissioner Dreyzehner identified the obvious link between opioid sales and opioid related health problems, noting "the incredible correlation between sales and supply and availability [of opioids] and opioid related deaths and opioid treatment admissions."<sup>202</sup>

447. Additionally, Dr. Stephen Loyd, Medical Director of the Tennessee Department of Mental Health and Substance Abuse Services, recently testified before the Tennessee House of Representatives' Opioid Task Force ("House Opioid Task Force") that: "[m]arketing of opioids as having a low addictive potential when used for the treatment of chronic pain" resulted in "opioids prescribed more freely by practitioners," and, in turn, an "increase in number of babies born drug dependent." <sup>203</sup>

<sup>&</sup>lt;sup>200</sup> U.S. Dep't of Justice, Appalachia High Intensity Drug Trafficking Area, CY2015 Annual Report, at 4 (2015).

National DEC, "Neonatal Abstinence Syndrome A Tennessee Perspective," Vimeo, May 4, 2015. Available at: <a href="https://vimeo.com/126839454">https://vimeo.com/126839454</a> (emphasis added).

<sup>&</sup>lt;sup>203</sup> House Opioid Task Force, February 23, 2017.

- 448. The Nationwide epidemic of NAS has a focal point in Tennessee.<sup>204</sup> The statistics are alarming:<sup>205</sup>
  - a. in 2015, 12.1 of every 1,000 babies were born with NAS in Tennessee;
  - b. in 2016, 12.2 of every 1,000 babies were born with NAS in Tennessee;
  - c. in 2017, 13.5 of every 1,000 babies were born with NAS in Tennessee;
- Among other issues, NAS babies experience long-term difficulties, including but not limited to the following types of effects: poor performance in school;<sup>206</sup> higher risk of developmental disabilities and the accompanying need for special needs services;<sup>207</sup> and lower cognitive function.<sup>208</sup> Thus, the Baby Doe Plaintiffs will likely suffer long-term effects that will require lifelong treatment and special education expenses, and the Baby Doe Plaintiffs may suffer sustained (perhaps lifelong) cognitive impairments.

# M. <u>In Addition to Death and NAS, the Opioid Abuse and Diversion Enabled by</u> Defendants has Other Deleterious Economic and Societal Consequences

450. In addition to these health effects, the flood of opioids into Tennessee corresponds to lost productivity and increases in crime, children in State custody, and treatment and healthcare

<sup>&</sup>lt;sup>204</sup> The TN Department of Health has tracked statistics related to babies with NAS from which the following statistical data has been gathered. Available at: <a href="https://www.tn.gov/health/article/nas-update-archive.html">https://www.tn.gov/health/article/nas-update-archive.html</a>.

 $<sup>\</sup>overline{205}$  Id.

<sup>&</sup>lt;sup>206</sup> Neonatal Abstinence Syndrome and High School Performance (Jan. 16, 2017), available at: <a href="http://i2.cdn.turner.com/cnn/2017/images/01/16/neonatal.abstinence.syndrome.and.high.school.p">http://i2.cdn.turner.com/cnn/2017/images/01/16/neonatal.abstinence.syndrome.and.high.school.p</a> erformance.pdf.

https://consumer.healthday.com/pregnancy-information-29/pregnancy-drugs-news-545/babies-born-addicted-to-opioids-often-struggle-with-learning-722293.html (summarizing results of CDC study of NAS-born babies in Tennessee).

<sup>&</sup>lt;sup>208</sup> Nygaard, Egil, et al., Longitudinal Cognitive Development of Children Born to Mothers with Opioids and Polysubstance Abuse, Pediatric RESEARCH, Vol. 28 No. 3 (Sept. 2015).



costs.<sup>209</sup> In a 2013 report, the State of Tennessee itself identified prescription drug as the cause of these deleterious effects:<sup>210</sup>

# SUMMARY OF THE PRESCRIPTION DRUG EPIDEMIC IN TENNESSEE

## Who Abuses Prescription Drugs?

- In 2012, prescription opioids became the primary substance of abuse for people in Department of Mental Health and Substance Abuse Services-funded treatment, overtaking alcohol for the first time.
- Almost 5% of Tennesseans have used pain relievers in the past year for non-medical purposes.
- Young adults (18-25-year-olds) in Tennessee are using prescription opioids at a 30% higher rate than the national average.

### Access to Prescription Drugs

- High Number of Prescriptions Dispensed
  - There were 25% more controlled substances dispensed in Tennessee in 2012 than in 2010.
- Doctor Shopping
  - In March 2013, 2,010 people received prescriptions for opioids or benzodiazepines from four or more prescribers.
- Prescribing Practices
  - As of August 1, 2013, 25 physicians had been prosecuted for overprescribing during 2013.
- Sources of Prescription Drugs
  - More than 70% of people who use prescription drugs for non-medical reasons got them from a friend or relative.

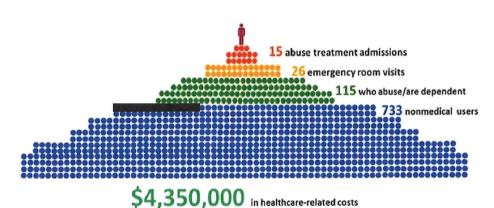
## Consequences of Prescription Drug Abuse

- Healthcare Costs
  - The number of emergency department visits for prescription drug poisoning has increased by approximately 40% from 2005 to 2010.
- Overdose Deaths
  - There has been a 220% increase in the number of drug overdose deaths from 1999 to 2012 (342 in 1999 to 1,094 in 2012).
- Criminal Justice System Involvement
  - Drug-related crimes against property, people and society have increased by 33% from 2005 to 2012.
- Lost Productivity
  - The cost of lost productivity due to prescription drug abuse in Tennessee was \$142.9 million in 2008. This number adjusted for 2013 inflation is \$155.2 million.
- Children in State Custody
  - About 50% of the youth taken into Department of Children's Services custody resulted from parental drug use.
- Neonatal Abstinence Syndrome
  - Over the past decade, we have seen a nearly ten-fold rise in the incidence of babies born with Neonatal Abstinence Syndrome in Tennessee.
- Treatment Costs
  - It is estimated that the cost of providing state-funded treatment services to individuals that abuse prescription drugs and live below the poverty level would cost \$27,933,600.

<sup>&</sup>lt;sup>209</sup> "Prescription for Success" at p. 9.

<sup>&</sup>lt;sup>210</sup> Id.

451. As the graphic below reflects, opioid overdose deaths represent only the "tip of the iceberg" of the human and societal costs of the opioid epidemic:<sup>211</sup>



For every 1 opioid overdose death in 2010 there were...

452. According to a recent article by the Tennessean, the "substance abuse epidemic – most notably involving opioids" -- costs Tennessee more than \$2 billion annually. That \$2 billion annual price tag includes \$46 million for babies born in Tennessee with NAS; \$422.5 million for hospitalizations associated with opioid abuse; and another \$372,440 in emergency room visits associated with opioid abuse. However, the largest component of the substantial yearly costs is the \$1.29 billion in "lost income from having an estimated 31,000 people, or 1 percent of the workforce, out of jobs. As the article further explains:

<sup>&</sup>lt;sup>211</sup> Benjamin Schachtman, 'Closer to Home' – The Cost of the Opioid Epidemic May be the Tip of the Iceberg, portcitydaily.com, Apr. 3, 2017 (attributing graphic chart to the N.C. Public Health Department). Available at: <a href="http://portcitydaily.com/2017/04/03/closer-to-home-the-cost-of-the-opioid-epidemic-may-be-the-tip-of-the-iceberg/">http://portcitydaily.com/2017/04/03/closer-to-home-the-cost-of-the-opioid-epidemic-may-be-the-tip-of-the-iceberg/</a>.

<sup>&</sup>lt;sup>212</sup> Holly Fletcher, *Drug, alcohol abuse saps \$2 billion from Tennessee annually – an under-the-radar impact of the opioid epidemic*, USA TODAY NETWORK – Tennessee (Dec. 3, 2017). Available at: <a href="https://www.tennessean.com/story/money/industries/health-care/2017/12/04/drug-alcohol-abuse-saps-2-billion-tennessee-annually-under-the-radar-impac">https://www.tennessean.com/story/money/industries/health-care/2017/12/04/drug-alcohol-abuse-saps-2-billion-tennessee-annually-under-the-radar-impac</a>.

<sup>&</sup>lt;sup>213</sup> *Id*.

<sup>214</sup> Id.

Teresa Waters, the chair of preventive medicine at the University of Tennessee Health Sciences Center and person responsible for compiling the data used in the Tennessean article, said she "took a conservative approach to the analysis so the overall economic impact and state spending is likely higher." In particular, Waters noted that "she didn't include costs associated with substance abuse overdoses because of debate over how to estimate economic impact from early loss of life."<sup>215</sup>

- 453. Defendants' creation and/or expansion of the opioid market has given rise to a market for heroin in Tennessee, made up largely of addicts who can no longer afford diverted prescription opioids available on the black market. There is a relationship between opioid pain reliever use and heroin use. According to the federal government's National Survey on Drug Use and Health, four out of five heroin addictions begin with opioid prescription pain relievers.<sup>216</sup>
- 454. On November 13, 2015, E. Douglas Varney, Commissioner of the Tennessee Department of Mental Health, issued a message detailing the recent rise of heroin abuse in Tennessee. In the message, Varney explained that, as the state "forged efforts to reduce availability of opioid based pain remedies, in the shadows, heroin arrived on the scene. It arrived like a tidal wave in Tennessee. It's a far more potent form of opioids, cheaper, more dangerous and more lethal." Varney referenced data from multiple sources showing heroin, and heroin-related criminal activity, sharply on the rise, and said: "I'm saddened to see our friends and

2013.htm.

 $<sup>^{215}</sup>$  *Id*.

Pradip K. Muhuri et al., Substance Abuse and Mental Health Services Administration, Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States (August 2013), available at: <a href="http://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-">http://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-</a>

<sup>&</sup>lt;sup>217</sup> TN Dep't of Mental Health and Substance Abuse Services, Message from Commissioner E. Douglas Varney on Heroin's Grip in our Cities and Suburbs (Nov. 13, 2015), available at: <a href="https://www.tn.gov/behavioral-health/news/20176">https://www.tn.gov/behavioral-health/news/20176</a>.

neighbors that have been struggling with opioid addiction now transitioning to heroin which is coming from the criminal underground street dealer."<sup>219</sup>

- 455. In a December 2016 publication of the Tennessee Medical Association titled "No Easy Fix: Tennessee's Doctors Take on The Opioid Abuse Epidemic," Dr. Roland W. Gray described the opioid epidemic as the "worst and deadliest drug epidemic in our nation's history."<sup>220</sup> He went on to say that "[t]here's good news in that we are prescribing significantly fewer opiates in Tennessee; the bad news is they are being replaced by a heroin epidemic. Tennesseans are rapidly turning to those drugs they're available on the street and are cheaper and far more powerful than prescription opiates."<sup>221</sup>
- 456. According to the Tennessee Department of Health, heroin-associated overdose deaths are also on the rise, increasing from 147 in 2014 to 205 in 2015. 222
- 457. Commissioner Dreyzehner has determined that "[t]here is a direct correlation between opioid addiction and heroin use." 223
- 458. As set forth in a September 2016 report by the Tennessee Department of Mental Health and Substance Abuse Services, people with prior treatment admissions, people who inject opioids, people ages 25-34, and people who started opioid use after age 18 are all at increased risk for switching from prescription opioids to heroin.<sup>224</sup>

<sup>&</sup>lt;sup>219</sup> *Id*.

<sup>&</sup>lt;sup>220</sup> Roland W. Gray, *The Good News/Bad News About Tennessee's Opioid Epidemic*, 109 Tenn. Med.. 4, 23 (2016), available at:

https://www.tnmed.org/Documents/TennMed-Qtr4-05FINAL.pdf.

<sup>&</sup>lt;sup>221</sup> *Id*.

<sup>&</sup>lt;sup>222</sup> Tenn. Dep't of Health, 1,451 Tennesseans Die from Drug Overdoses in 2015, tn.gov (Nov. 15, 2016). Available at: http://tn.gov/health/news/46773.

<sup>&</sup>lt;sup>223</sup> Working Group Report.

<sup>&</sup>lt;sup>224</sup> K. Edwards, Tennessee Department of Mental Health & Substance Abuse Services, *Turning the Curve on Opioid and Heroin Abuse in Tennessee*, 14 (September 14, 2016).



# N. The Baby Doe Plaintiffs' Neonatal Abstinence Syndrome was a Result of Defendants' Participation in the Illegal Drug Market

459. The biological mothers of the Baby Doe Plaintiffs became addicted to opioids and maintained their addictions using diverted opioids as a result of Defendants' participation in the illegal drug market. While Defendants callously and cynically profited from their addiction and the illegal market which fueled it, these women gave birth to the Baby Doe Plaintiffs, each of whom, from their first breaths to today, suffer from their *in utero* exposure to opioids.

## 1. Baby Doe and Brother Doe

- 460. Mary Doe, the biological mother of Plaintiffs Baby Doe and Brother Doe, consumed illegal opioids during her pregnancy with each child.
- 461. Mary Doe first began taking opioids pursuant to lawful prescriptions beginning in her late teens.
  - 462. Soon thereafter, Mary Doe became addicted to opioids.
- 463. As her addiction worsened, Mary Doe turned to the streets to buy pills on the black market to feed her addiction, including Roxicodone, hydromorphone, and Opana.
- 464. Still addicted, on June 18, 2013, Mary Doe gave birth to Brother Doe at Vanderbilt University Medical Center in Davidson County. Brother Doe was diagnosed with NAS and treated for withdrawal symptoms until he was discharged.
- 465. Still addicted, on July 8, 2015, Mary Doe gave birth to Baby Doe at Vanderbilt University Medical Center in Davidson County. Baby Doe was diagnosed with NAS and treated for withdrawal symptoms until he was discharged.
- 466. Baby Doe and Brother Doe suffered tremendously following their births: arching their backs, refusing to eat, and crying uncontrollably as they suffered from withdrawal symptoms as a result of their opioid exposure.



467. Baby Doe and Brother Doe continue to suffer from numerous behavioral issues to this day, and their parents worry that they will have lasting learning disabilities and future addiction issues as a result of their drug exposure *in utero*.

## 2. Baby Roe, Brother Roe, and Sister Roe

- 468. Mary Roe, the biological mother of Baby Roe, Brother Roe, and Sister Roe consumed illegal opioid drugs during her pregnancy with each child.
- 469. Mary Roe first began taking opioids as a teenager pursuant to a lawful prescription after an accident.
  - 470. Soon thereafter, she became addicted.
- 471. As her addiction worsened, Mary Roe turned to the streets to buy pills on the black market to feed her addiction, including Percocet, Roxicodone, Opana, Lortab, and Fentanyl.
- 472. Still addicted, on February 24, 2014, Mary Roe gave birth to Sister Roe at Centennial Women's Hospital in Davidson County. Sister Roe was diagnosed with NAS and was treated for withdrawal symptoms until she was discharged.
- 473. Still addicted, on December 2, 2015, Mary Roe gave birth to Brother Roe at Vanderbilt University Medical Center in Davidson County. Brother Roe was diagnosed with NAS and treated for withdrawal symptoms until he was discharged.
- 474. Still addicted, on May 15, 2017, Mary Roe gave birth to Baby Roe at Vanderbilt University Medical Center in Davidson County. Baby Roe was diagnosed with NAS and treated for withdrawal symptoms until he was discharged.
- 475. Baby Roe, Brother Roe, and Sister Roe suffered tremendously following their births: arching their backs, refusing to eat, and crying uncontrollably as they suffered from withdrawal symptoms as a result of their opioid exposure.

476. Baby Roe, Brother Roe, and Sister Roe continue to suffer from numerous behavioral issues to this day, and their parents worry that they will have lasting learning disabilities and future addiction issues as a result of their drug exposure *in utero*.

## 3. Baby Smith

- 477. Mary Smith, the biological mother of Baby Smith, consumed illegal opioids she obtained from the black market, including Percocet and Lortab, among others.
- 478. Still addicted, on May 1, 2020, Mary Smith gave birth to Baby Smith at Centennial Medical Center in Davidson County. The umbilical cord drug screen came back positive for morphine, hydromorphone, and hydrocodone. Baby Smith was diagnosed with NAS and treated for withdrawal symptoms until he was discharged into the custody of Mary Smith's cousin (who has since obtained legal custody of Baby Smith).
- 479. Baby Smith suffered tremendously following his birth: arching his back, refusing to eat, and crying uncontrollably as he suffered from withdrawal symptoms as a result of his opioid exposure.
- 480. Baby Smith continues to suffer from numerous behavioral issues to this day, and his guardian worries that he will have lasting learning disabilities and future addiction issues as a result of his drug exposure *in utero*.
- 481. The Baby Doe Plaintiffs' NAS and associated conditions are consequences of the illegal market in which the Defendants participated. Defendants knew that their acts and omissions with regards to the marketing, distribution, and dispensing of opioids would result in a community of addicts, that those addicts would likely seek opioids through illegal distribution channels, and that many of those addicts—such as Mary Doe, Mary Roe, and Mary Smith—would give birth to babies dependent on opioids.

482. The Baby Doe Plaintiffs are just six of the thousands of innocent infants victimized by Defendants' unlawful conduct. For years to come, these children will have to bear the psychological, physical, and financial burdens of these Defendants' campaign to addict America to opioids.

## THE THCLA DOES NOT APPLY

- 483. Tennessee's Healthcare Liability Act does not apply to this DDLA action or any other claims made in this lawsuit. While the THCLA applies to "any civil action...alleging that a health care provider or providers have caused an injury relating to the provision of, or failure to provide, health care services to a person," Tenn. Code Ann. § 29-26-101(a)(1), the DDLA is distinct in that defendants are liable only for "injury resulting from an individual's use of an illegal drug." Tenn. Code Ann. § 29-38-105(a). Plaintiffs have no burden of establishing direct or proximate causation between defendants' alleged provision of health care services; instead, Plaintiff's evidentiary burden with regard to Defendants' conduct is to show "[t]he defendant's participation in the illegal drug market was connected with the same type of illegal drug used by the individual drug user." Tenn. Code Ann. § 29-38-106(b)(2)(B). Absent a causal link to the damages alleged herein, Defendants' conduct does not fall under the umbrella of the THCLA.
- 484. Without conceding that Tennessee's Healthcare Liability Act applies to any claim brought in this action, or that a certificate is required under the Tennessee Healthcare Liability Act for any claim brought in this action, and pled in the alternative, to the extent necessary, Plaintiffs have complied with the certificate of good faith requirement of the Tennessee Healthcare Liability Act, Tenn. Code Ann. § 29-26-101, et seq, which has been interpreted as a jurisdictional requirement. Pursuant to Tenn. Code Ann. § 29-26-122(a), a Certificate of Good Faith signed by the undersigned counsel is included as Exhibit A and incorporated herein by reference.

## **CAUSES OF ACTION**

## COUNT I TENNESSEE DRUG DEALER LIABILITY ACT

- 485. The Baby Doe Plaintiffs incorporate all preceding paragraphs by reference.
- 486. The Baby Doe Plaintiffs have been exposed to illegal opioids *in utero* because of their birth mothers' addiction to, purchase, and use of those illegal drugs. Those exposures provide them the right to sue for damages under the DDLA. Tenn. Code Ann. § 29-38-106(a)(2).
- 487. Mary Doe, the birth mother of Plaintiffs Baby Doe and Brother Doe, was an "individual drug user" under Tenn. Code Ann. § 29-38-104(4) whose illegal drug use attributable to illegal opioids resulted in *in utero* opioid exposure during her respective pregnancies with Baby Doe and Brother Doe. Tenn. Code Ann. § 29-38-104(4).
- 488. Mary Doe's opioid use was illegal in that she used opioids obtained without a valid prescription as required by Tenn. Code Ann. § 53-11-308(a).
- 489. Mary Doe bought and used illegal opioids throughout Davidson County, Tennessee, including Roxicodone, hydromorphone, and Opana. Under the DDLA, the legislative districts in Davidson County is the "place of illegal drug activity." Tenn. Code Ann. § 29-38-104(12).
- 490. Mary Roe, the birth mother of Plaintiffs Baby Roe, Brother Roe, and Sister Roe was an "individual drug user" under Tenn. Code Ann. § 29-38-104(4) whose illegal drug use attributable to illegal opioids resulted in *in utero* opioid exposure during her respective pregnancies with Baby Roe, Brother Roe, and Sister Roe.
- 491. Mary Roe's opioid use was illegal in that she used opioids obtained without a valid prescription as required by Tenn. Code Ann. § 53-11-308(a).

- 492. Mary Roe bought and used illegal opioids throughout Davidson County, Tennessee, including Percocet, Roxicodone, Opana, Lortab, and fentanyl. Under the DDLA, the legislative districts in Davidson County is the "place of illegal drug activity." Tenn. Code Ann. § 29-38-104(12).
- 493. Mary Smith, the birth mother Plaintiff Baby Smith, was an "individual drug user" under Tenn. Code Ann. § 29-38-104(4) whose illegal drug use attributable to illegal opioids resulted in *in utero* opioid exposure during her pregnancy with Baby Smith.
- 494. Mary Smith's opioid use was illegal in that she used opioids obtained without a valid prescription as required by Tenn. Code Ann. § 53-11-308(a).
- 495. Mary Smith bought and used illegal opioids throughout Davidson County, Tennessee, including Percocet and Lortab. Under the DDLA, the legislative districts in Davidson County is the "place of illegal drug activity." Tenn. Code Ann. § 29-38-104(12).
- 496. Defendants knowingly participated in the production, procurement of the originally diverted prescription, and/or distribution of prescription opioids into the illegal market that reached the Baby Doe Plaintiffs' community during all times relevant to this complaint. For purposes of the DDLA, Defendants' "illegal drug market target community" is the entire state of Tennessee, because Defendants participated in the illegal drug market by distributing 4 ounces or more of a "specified illegal drug." Tenn. Code Ann §§ 29-38-104(8), 29-38-109(4). As noted by the Tennessee Department of Health in a 2015 presentation, the Tennessee market for hydrocodone and oxycodone pills comprised of 51 hydrocodone pills and 21 oxycodone pills for every Tennessean. Commissioner of Health Dreyzehner noted that 50% of mothers of NAS babies obtained their pills, in whole or in part, from diverted pills (28.7% solely from diverted drugs). Given that a single oxycodone tablet, on information and belief, weighs approximately 135 mg

and contains at least 10 mg of opioid, there can be no question that each of the Drug Producer Defendants far exceeded the four-ounce level, and the same holds true as to the Distributor Defendants and Pharmacy Chain Defendants. The Pill Mill Defendants also exceed the four-ounce level.

497. The Producer Defendants, Distributor Defendants, and Pharmacy Chain Defendants all recognized that they had a responsibility not to procure or fill suspicious orders, not to convince prescribers to write scripts without a valid medical purpose, and not to supply channels of distribution that they knew or reasonably expected would result in diversion. Nevertheless, they violated these responsibilities through the various acts referenced herein.

498. Under Tennessee law, prescription opioids are controlled substances because they inherently have a "high potential for abuse" and that "may lead to severe psychic or physical dependence." For this reason, everyone who handles prescription opioids in Tennessee (from production to retail sales) must maintain appropriate safeguards against abuse and diversion, and must ensure that the drugs are only being distributed to serve legitimate medical purposes. If either or both of these preconditions is not satisfied, it is unlawful to distribute prescription opioids in Tennessee. Indeed, entities holding a Tennessee license can be criminally prosecuted for violating their responsibilities in the distribution chain. The Producer Defendants, Distributor Defendants, Pharmacy Chain Defendants, and Pill Mill Defendants did not lawfully distribute prescription opioids into or within Tennessee. Instead, using their licenses as a cover, they unlawfully distributed drugs without maintaining necessary controls (rendering the distribution

<sup>&</sup>lt;sup>225</sup> Tenn. Code Ann. § 39-17-407.

<sup>&</sup>lt;sup>226</sup> See, e.g., Tenn. Code Ann. § 53-11-302 and -303; Rules of Tn Bd. of Pharmacy, Ch. 1140-02.01 et seq. and Ch. 1140-09.01 et seq.

<sup>&</sup>lt;sup>227</sup> See Tenn. Code Ann. § 53-11-401(a).

unlawful), knowingly distributed those drugs into channels that they knew were resulting in diversion, knowingly encouraged high-volume pill mill prescribers to prescribe opioids without a legitimate medical purpose to feed drug abusers, pill seekers, and drug dealers, knowingly supplied pharmacies serving pill mills, and knowingly dispensed prescriptions that were not made for a legitimate medical purpose.

- 499. The Producer Defendants also committed various other acts intended to facilitate the marketing or distribution of illegal opioids that reached the Baby Doe Plaintiffs for purposes of Tenn. Code Ann. § 29-38-104(9). These acts are detailed in the preceding paragraphs, which are incorporated by reference. Those acts include, but are not limited to:
  - **a.** engaging in a mass marketing campaign to downplay the risks of addiction from long-term use of opioids of non-cancer pain;
  - **b.** taking actions that violated DEA and FDA requirement or guidelines regarding the marketing and promotion of their drugs and/or suspicious order monitoring;
  - c. utilizing front groups and key opinion leaders to spread misinformation regarding the risks of addiction and the signs of addiction;
  - **d.** utilizing marketing teams to devise ways to overcome the legitimate concerns of Tennessee prescribers regarding long-term use of opioids;
  - e. successfully encouraging Tennessee prescribers to engage in prescription practices that defendants knew and expected would drive up addiction rates;
  - f. oversupplying Tennessee and Plaintiffs' community with opioids, knowing that the oversupply would necessarily feed and expand the black market;
  - g. targeting the highest-volume Tennessee prescribers for sales efforts and calling on these prescribers repeatedly to convince them to prescribe more opioids;
  - h. using volume-based bonuses and commissions for sales representatives with respect to a highly addictive and widely abused narcotic, and otherwise encouraging and rewarding sales representatives for doing business with Tennessee pill mills and other over-prescribers;

- i. knowingly establishing business relationships with Tennessee pill mills and over-prescribers to compete for their business by convincing them to prescribe more opioids, including high-volume prescribers in small, rural Tennessee communities who were prescribing opioids at unjustifiable levels;
- j. directly pushing Tennessee prescribers (through frequent calls, in-person visits, and promotions) to prescribe more opioids after it was clear, even by defendants' own stated criteria, that those prescribers were engaging in highly suspicious prescribing practices or criminal conduct;
- k. directly pushing Tennessee prescribers (through frequent calls, in-person visits, and promotions) to prescribe more opioids after receiving reports from law enforcement that the prescribers and pharmacies were supplying drug addicts and the illegal market;
- I. establishing new accounts with high-volume opioid prescribers without due diligence, knowing that the new account may be a pill mill;
- m. providing patients or Tennessee prescribers incentives to prescribe more opioids;
- convincing naïve Tennessee doctors willingly to write prescriptions for powerful opioids to pill seekers and prescription drug abusers who sell the prescriptions wholesale;
- directly pushing Tennessee prescribers (through frequent calls, in-person visits, and promotions) to prescribe more opioids when defendants knew that those prescribers were likely engaging in unlawful conduct and feeding the illegal drug market;
- **p.** incentivizing sales representatives to do business both with Tennessee pill mills and with pharmacies supplying pill mills (and financially rewarding those sales associates for doing so);
- **q.** filling suspicious orders intended for distribution in Tennessee despite knowing that the orders reflected diversion;
- **r.** implementing sham suspicious order monitoring programs that were structured to fail and to allow diversion to proceed unimpeded in Tennessee and elsewhere;
- s. filling orders that defendants had subjectively identified as suspicious before undertaking or completing an investigation into those orders;

- t. permitting sales representatives to call on or prescriber or pharmacy even after internally recommending that the entity be reported to the DEA;
- u. in the case of Endo, knowingly selling a product for 9 months after Endo told the FDA that the product was so rampantly abused and diverted that it had to be removed from the market to avoid addiction, diversion, and overdose deaths, then returning to profit-share from sales of that product from 2017 forward;
- continuing to call on pill mill prescribers and associated pharmacies even after being told by law enforcement that they were likely feeding the illegal drug market;
- w. collaborating with the Drug Distributors to provide sham justifications to fill suspicious orders;
- x. placing primary or sole responsibility for suspicious order monitoring in the hands of a commission/volume bonus-based sales force with an inherent conflict of interest;
- y. allowing inherently conflicted sales representatives to "clear" suspicious orders without any independent investigation;
- z. allowing sales associate to determine whether to self-report their best customers even where the stated criteria for reporting diversion are met; and
- **aa.** supplying outlandish volumes of prescription opioids to rural Tennessee communities far exceeding any conceivable medical need.
- 500. The Distributor Defendants and the Pharmacy Chain Defendants also committed acts intended to facilitate the marketing or distribution of illegal opioids that reached the Baby Doe Plaintiffs for purposes of Tenn. Code Ann. § 29-38-104(9). These acts are detailed in the preceding paragraphs, which are incorporated by reference. Those acts include, but are not limited to:
  - **a.** providing volume-based bonuses or commissions to sales representatives relating to shipment of a highly addictive and widely abused narcotic;
  - **b.** incentivizing or otherwise rewarding sales personnel who did business with pharmacies that supply pill mills and other over-prescribers;

- c. routinely filling suspicious orders, including that should have been flagged as suspicious and impounded based on the Drug Distributors' and Walmart's own stated criteria (such as orders of unusual size or frequency);
- **d.** routinely filling orders, including plainly suspicious orders, without due diligence;
- e. establishing new accounts without due diligence;
- **f.** implementing a suspicious order marketing program that was designed to fail;
- g. making adjustments to the suspicious order monitoring program to make it less effective on purpose, such as changing thresholds for customers that initially exceeded them;
- **h.** providing sham justifications to "clear" orders from being impounded or accounts from being frozen through chargeback restrictions;
- i. intentionally seeking out relationships with pain clinics or pharmacies that serve pain clinics;
- j. shipping excessive amounts of opioids to pharmacies and dispensing physicians in Tennessee at levels far exceeding any conceivable legitimate need, where the volume of pills far exceeded the number of people, and where the prescription per capita rate was exceedingly high; and
- **k.** shipping excessive amounts of opioids to pharmacies and dispensing physicians in Tennessee, despite reports from law enforcement, firsthand observations, or other knowledge that the pharmacy was honoring pill mill prescriptions *en masse*.
- 501. The Pill Mill Defendants also committed acts intended to facilitate the marketing and distribution of illegal opioids that reached the Baby Doe Plaintiffs for purposes of Tenn. Code Ann. § 29-38-104(9). These acts are detailed in the preceding paragraphs, which are incorporated by reference.
- 502. As a result, the Producer Defendants, Distributor Defendants, and Pharmacy Chain Defendants knowingly disseminated massive quantities of prescription opioids to suspect

physicians, pharmacies, and into the black market, including to "pill mills" such as the Pill Mill Defendants

503. The Defendants committed acts intended to facilitate the marketing or distribution of illegal opioids that resulted in the Baby Doe Plaintiffs being exposed to opioids *in utero*. Tenn. Code Ann. § 29-38-104(9).

## PRAYER FOR RELIEF

## WHEREFORE, the Baby Doe Plaintiffs demand judgment as follows:

- 1. Economic damages in an amount to be proven at trial. Under the DDLA, "[e]conomic damages, including, but not limited to: the cost of treatment and rehabilitation, medical expenses, loss of economic or educational potential, loss of productivity, absenteeism, support expenses, accidents or injury, and any other pecuniary loss proximately caused by the illegal drug use" described in this Complaint. Tenn. Code Ann. § 29-38-106(c)(1);
- 2. Non-economic damages in an amount to be proven at trial. Under the DDLA, "[n]on-economic damages, including, but not limited to, physical and emotional pain, suffering, physical impairment, emotional distress, mental anguish, disfigurement, loss of enjoyment, loss of companionship, services and consortium and other nonpecuniary losses proximately caused by an individual's use of an illegal drug." Tenn. Code Ann. § 29-38-106(c)(2);
  - 3. Exemplary/punitive damages;
- 4. Awards from all Defendants, including but not limited to the costs and disbursements of this action, reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses as provided by the common fund doctrine and other applicable law pursuant to Tenn. Code Ann. §29-38-106(c)(3) (4)-(5);
  - 5. Declaratory relief;

- 6. All other remedies and relief available under law; and
- 7. Such other and further relief as the Court deems just and proper.

The Plaintiffs demand a trial by jury on all issues except for attorney's fees and costs

Filed on this 3rd day of August 2022

Respectfully submitted,

/s/ Tricia R. Herzfeld

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# EXHIBIT A

# EFILED 08/03/22 02:25 PM CASE NO. 22C1563 Richard R. Rooker, Clerk

# IN THE CIRCUIT COURT FOR THE TWENTIETH JUDICIAL DISTRICT DAVIDSON COUNTY, TENNESSEE

BABY DOE and BROTHER DOE; BABY ROE, BROTHER ROE, and SISTER ROE; and BABY SMITH, by and through their guardian <i>ad litem</i> ,	) ) ) )
Plaintiffs,	
v.	)
ENDO HEALTH SOLUTIONS, INC.; ENDO PHARMACEUTICALS, INC.; PAR PHARMACEUTICAL, INC.; PAR PHARMACEUTICAL COMPANIES, INC. f/k/a PAR PHARMACEUTICAL HOLDINGS, INC.; IMPAX LABORATORIES; AMNEAL PHARMACEUTICALS, INC.; AMNEAL PHARMACEUTICALS, LLC; TEVA PHARMACEUTICALS USA, INC.; ALLERGAN FINANCES, LLC; ACTAVIS, LLC; ACTAVIS PHARMA	) ) ) ) ) Civil Action No.: )  JURY DEMAND ) ) ) )
INC.; WATSON LABORATORIES; JOHNSON & JOHNSON, INC.; JANSSEN PHARMACEUTICALS,	) ) )
INC.; AMERISOURCEBERGEN DRUG CORPORATION; CARDINAL HEALTH, INC.;	) )
MCKESSON CORPORATION; CVS PHARMACY, INC; CVS TN	) ) )
DISTRIBUTION, LLC; CVS INDIANA, LLC; TENNESSEE CVS PHARMACY, LLC;	) ) )
RITE AID HDQTRS. CORP.; RITE AID OF TENNESSEE, INC.; RITE AID OF MARYLAND, INC. d/b/a RITE AID	) )
MID-ATLANTIC CUSTOMER SUPPORT CENTER, INC.;	) )
WALGREEN CO.; WALMART INC.; WAL-MART STORES EAST, L.P.;	) ) )
TIMOTHY ABBOTT;	

CINDY SCOTT;	)
HEMAL MEHTA;	)
<b>HEATHER MARKS</b> ;	)
JAMES MACCARONE; and	)
DEL MAR MEDICAL, INC. d/b/a	)
PARDUE'S PHARMACY,	)
	)
Defendants.	)

## **CERTIFICATE OF GOOD FAITH**

Without conceding that T.C.A. § 29-26-122 applied to the claims asserted by the Plaintiffs in the above-styled action and without conceding that the above-styled case is a "healthcare liability action" as that term is defined by Tenn. Code Ann. § 29-26-101, Plaintiffs submit the following Certificate of Good Faith to comply with that statute's requirements. This is done out of an abundance of caution and should not be construed in any way as an admission that Tenn. Code Ann. § 29-26-122 applies to any claims advanced in the above-styled lawsuit.

- A. In accordance with T.C.A. § 29-26-122, I hereby state the following: (Check item 1 or 2 below and sign your name beneath the item you have checked, verifying the information you have checked. Failure to check item 1 or 2 and/or not signing item 1 or 2 will make this case subject to dismissal with prejudice.)
- The plaintiff or plaintiff's counsel has consulted with one (1) or more experts who have provided a signed written statement confirming that upon information and belief they:
  - (A) Are competent under § 29-26-115 to express opinion(s) in the case; and
  - (B) Believe, based on the information available from the medical records concerning the care and treatment of the Plaintiff for the incident(s) at issue, that there is a good faith basis to maintain the action consistent with the requirements of § 29-26-115.

Signature of Plaintiff if not represented, or Signature of Plaintiff's Counsel

or

- X 2. The Plaintiff or Plaintiff's counsel has consulted with one (1) or more experts who have provided a signed written statement confirming that upon information and belief they:
  - (A) Are competent under § 29-26-115 to express opinion(s) in the case; and

(B) Believe, based on the information available from the medical records reviewed concerning the care and treatment of the Plaintiff for the incident(s) at issue and, as appropriate, information from the Plaintiff or others with knowledge of the incident(s) at issue, that there are facts material to the resolution of the case that cannot be reasonably ascertained from the medical records or information reasonably available to the Plaintiff or Plaintiff's counsel; and that despite the absence of this information there is a good faith basis for maintaining the action as to each Defendant consistent with the requirements of § 29-26-115. Refusal of the defendant to release the medical records in a timely fashion, or where it is impossible for the plaintiff to obtain the medical records shall waive the requirement that the expert review the medical records prior to expert certification.

Signature of Plaintiff if not represented, or Signature of Plaintiff's Counsel

B. You MUST complete the information below and sign:

I have been found in violation of T.C.A. § 29-26-122 <u>0</u> prior times. (Insert number of prior violations by you.)

Siew RHefeld

Signature of Person Executing This Document

Sica RHafeld

<u>08/03/2022</u>

Date

## CIRCUIT COURT SUMMONS

NASHVILLE, TENNESSEE

Service ID 310468

STATE OF TENNESSEE DAVIDSON COUNTY 20™ JUDICIAL DISTRICT

**BABY DOE** 

Plaintiff

CIVIL ACTION
DOCKET NO. 22C1563
Method of Service:
Personal Service

VS.

Service ID 310468

ENDO HEALTH SOLUTIONS INC. 1209 ORANGE STREET THE CORPORATION TRUST COMPANY WILMINGTON, DE 19801

Defendant

To the above named Defendant:

You are summoned to appear and defend a civil action filed against you in the Circuit Court, 1 Public Square, Room 302, P.O. Box 196303, Nashville, TN 37219-6303, and your defense must be made within thirty (30) days from the date this Summons is served upon you. You are further directed to file your defense with the Clerk of the Court and send a copy to the Plaintiff's attorney at the address listed below.

In case of your failure to defend this action by the above date, judgment by default will be rendered against you for the relief demanded in the Complaint.

ISSUED: 08/03/2022

RICHARD R. ROOKER

Circuit Court Clerk

Davidson County, Tennessee

Deputy Clerk

ADDRESS OF PLAINTIFF'S ATTORNEY OR PLAINTIFF:

TRICIA R HERZFELD 223 ROSA L PARKS AVE. SUITE 200 NASHVILLE, TN 37203

## NOTICE TO THE DEFENDANT:

Tennessee law provides a Ten Thousand and 00/100 Dollars (\$10,000.00) debtor's equity interest personal property exemption from execution or seizure to satisfy a judgment. If a judgment should be entered against you in this action and you wish to claim property as exempt, you must file a written list, under oath, of the items you wish to claim as exempt with the Clerk of the Court. The list may be filed at any time and may be changed by you thereafter as necessary; however, unless it is filed before the judgment becomes final, it will not be effective as to any execution or garnishment issued prior to the filing of the list. Certain items are automatically exempt by law and do not need to be listed; these include items of necessary wearing apparel (clothing) for yourself and your family and trunks or other receptacles necessary to contain such apparel, family portraits, the family Bible, and school books. Should any of these items be seized, you would have the right to recover them. If you do not understand your exemption right or how to exercise it, you may wish to seek the counsel of a lawyer.



To request an ADA accommodation, please contact Dart Gore at (615) 880-3309

rev. 09/01/2018

Service ID 310468

## NASHVILLE, TENNESSEE

## CIRCUIT COURT SUMMONS

Service ID 310468

# STATE OF TENNESSEE DAVIDSON COUNTY 20<sup>TH</sup> JUDICIAL DISTRICT

**CIVIL ACTION BABY DOE DOCKET NO. 22C1563** Method of Service: Personal Service **Plaintiff** VS. ENDO HEALTH SOLUTIONS INC. 1209 ORANGE STREET THE CORPORATION TRUST COMPANY WILMINGTON, DE 19801 Defendant RETURN ON PERSONAL SERVICE OF SUMMONS I hereby certify and return that on the \_\_\_\_\_day of \_\_\_\_\_, 20\_\_\_, I: served this Summons and Complaint/Petition on \_\_\_\_\_ in the following manner: failed to serve this Summons within 90 days after its issuance because Sheriff/Process Server

To request an ADA accommodation, please contact Dart Gore at (615) 880-3309

rev. 09/01/2018

## CIRCUIT COURT SUMMONS

NASHVILLE, TENNESSEE

Service ID 310469

## STATE OF TENNESSEE DAVIDSON COUNTY 20™ JUDICIAL DISTRICT

**BABY DOE** 

Plaintiff

CIVIL ACTION DOCKET NO. 22C1563 Method of Service: Personal Service

VS.

ENDO PHARMACEUTICALS INC. 800 S. GAY STREET, SUITE 2021 CT CORPORATION SYSTEM KNOXVILLE, TN 37929

Defendant

To the above named Defendant:

You are summoned to appear and defend a civil action filed against you in the Circuit Court, 1 Public Square, Room 302, P.O. Box 196303, Nashville, TN 37219-6303, and your defense must be made within thirty (30) days from the date this Summons is served upon you. You are further directed to file your defense with the Clerk of the Court and send a copy to the Plaintiff's attorney at the address listed below.

In case of your failure to defend this action by the above date, judgment by default will be rendered against you for the relief demanded in the Complaint.

ISSUED: 08/03/2022

RICHARD R. ROOKER

Circuit Court Clerk

Davidson County, Tennessee

By: Blolling

Deputy Clerk

ADDRESS OF PLAINTIFF'S ATTORNEY OR PLAINTIFF:

TRICIA R HERZFELD 223 ROSA L PARKS AVE. SUITE 200 NASHVILLE, TN 37203

## NOTICE TO THE DEFENDANT:

Tennessee law provides a Ten Thousand and 00/100 Dollars (\$10,000.00) debtor's equity interest personal property exemption from execution or seizure to satisfy a judgment. If a judgment should be entered against you in this action and you wish to claim property as exempt, you must file a written list, under oath, of the items you wish to claim as exempt with the Clerk of the Court. The list may be filed at any time and may be changed by you thereafter as necessary; however, unless it is filed before the judgment becomes final, it will not be effective as to any execution or garnishment issued prior to the filing of the list. Certain items are automatically exempt by law and do not need to be listed; these include items of necessary wearing apparel (clothing) for yourself and your family and trunks or other receptacles necessary to contain such apparel, family portraits, the family Bible, and school books. Should any of these items be seized, you would have the right to recover them. If you do not understand your exemption right or how to exercise it, you may wish to seek the counsel of a lawyer.



To request an ADA accommodation, please contact Dart Gore at (615) 880-3309

Service ID 310468

## NASHVILLE, TENNESSEE

Sheriff/Process Server

## CIRCUIT COURT SUMMONS

Service ID 310469

# STATE OF TENNESSEE DAVIDSON COUNTY 20<sup>TH</sup> JUDICIAL DISTRICT

**CIVIL ACTION DOCKET NO. 22C1563 BABY DOE** Method of Service: Personal Service Plaintiff VS. ENDO PHARMACEUTICALS INC. 800 S. GAY STREET, SUITE 2021 CT CORPORATION SYSTEM KNOXVILLE, TN 37929 Defendant RETURN ON PERSONAL SERVICE OF SUMMONS I hereby certify and return that on the \_\_\_\_\_\_day of \_\_\_\_\_\_, 20\_\_\_\_, I: served this Summons and Complaint/Petition on \_\_\_\_\_ in the following manner: failed to serve this Summons within 90 days after its issuance because \_\_\_\_\_

To request an ADA accommodation, please contact Dart Gore at (615) 880-3309